

# Exhibit 12

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE DISTRICT OF NEW JERSEY

3                   \*\*\*\*\*

4           IN RE:   VALSARTAN, LOSARTAN,   MDL No. 2875  
5           AND IRBESARTAN PRODUCTS

6           LIABILITY LITIGATION                               HON ROBERT B.  
7   KUGLER

8                   \*\*\*\*\*

9           THIS DOCUMENT APPLIES TO ALL  
10           CASES

11

12                   \*\*\*\*\*

13

14                               - CONFIDENTIAL INFORMATION -  
15                               SUBJECT TO PROTECTIVE ORDER

16

17                               Remote Videotaped via Zoom  
18           Deposition of PENG DONG, commencing at 7:07  
19           a.m. Hong Kong time, on the 29th of March,  
20           2021, before Maureen O'Connor Pollard,  
21           Registered Diplomat Reporter, Realtime  
22           Systems Administrator, Certified Shorthand  
23           Reporter.

24

25                               - - -

26

27                               GOLKOW LITIGATION SERVICES  
28           877.370.3377 ph | 917.591.5672 fax  
29                               deps@golkow.com

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<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES: ALL PARTIES APPEARED REMOTELY</p> <p>2 FOR THE PLAINTIFFS:</p> <p>3 MAZIE SLATER KATZ &amp; FREEMAN, LLC</p> <p>4 BY: ADAM SLATER, ESQ.</p> <p>5 CHERYLL A. CALDERON, ESQ.</p> <p>6 CHRISTOPHER GEDDIS, ESQ.</p> <p>7 103 Eisenhower Parkway</p> <p>8 Roseland, New Jersey 07068</p> <p>9 973-228-9898</p> <p>10 aslater@mazieslater.com</p> <p>11 ccalderson@mazieslater.com</p> <p>12 cgeddis@mazieslater.com</p> <p>13 -and-</p> <p>14 HOLLIS LAW FIRM</p> <p>15 BY: IRIS SIMPSON, ESQ.</p> <p>16 8101 College Boulevard, Suite 260</p> <p>17 Overland Park, Kansas 66210</p> <p>18 800-701-3672</p> <p>19 iris@hollislawfirm.com</p> <p>20 -and-</p> <p>21 MORGAN &amp; MORGAN</p> <p>22 BY: STEPHANIE JACKSON, ESQ.</p> <p>23 20 North Orange Avenue, Suite 1600,</p> <p>24 Orlando, Florida 32801</p> <p>sjackson@forthepeople.com</p> <p>-and-</p> <p>FLEMING NOLAN JEZ, LLP</p> <p>BY: DAVID HOBBS, ESQ.</p> <p>2800 Post Oak Boulevard</p> <p>Houston, Texas 77056</p> <p>713-621-7944</p> <p>david_hobbs@fleming-law.com</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES (continued):</p> <p>2 FOR THE DEFENDANT AUROBINDO PHARMACEUTICALS:</p> <p>3 CAITLIN LAWLOR, ESQ.</p> <p>4 CIPRIANI &amp; WERNER, P.C.</p> <p>5 450 Sentry Parkway</p> <p>6 Blue Bell, Pennsylvania 19422</p> <p>7 610-567-0700</p> <p>8 clawlor@c-wlaw.com</p> <p>9 FOR THE DEFENDANT MYLAN PHARMACEUTICALS, INC.:</p> <p>10 FRANK H. STOY, ESQ.</p> <p>11 PIETRAGALLO GORDON ALFANO BOSICK &amp; RASPANTI, LLP</p> <p>12 One Oxford Centre</p> <p>13 Pittsburgh, Pennsylvania 15219</p> <p>14 412-263-1840</p> <p>15 fhs@pietragallo.com</p> <p>16 Interpreter: Dr. Yang Shao</p> <p>17 Check Interpreters: Phil Hughes</p> <p>18 I Ching Ng</p> <p>19 Videographer: Henry Marte</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES (Continued):</p> <p>2 FOR THE PLAINTIFFS:</p> <p>3 FARR LAW FIRM</p> <p>4 BY: GEORGE T. WILLIAMSON, ESQ.</p> <p>5 99 Nesbit Street</p> <p>6 Punta Gorda, Florida 33950</p> <p>7 941-639-1158</p> <p>8 gwilliamson@farr.com</p> <p>9 FOR THE DEFENDANTS TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS SA, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC.:</p> <p>10 KATE M. WITTLAKE, ESQ.</p> <p>11 GREENBERG TRAURIG LLP</p> <p>12 4 Embarcadero Center, Suite 3000</p> <p>13 San Francisco, California 94111</p> <p>14 415-655-1285</p> <p>15 wittlakek@gtlaw.com</p> <p>16 FOR THE DEFENDANTS ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., PRINSTON PHARMACEUTICAL INC., HUAHAI U.S., INC., and SOLCO HEALTHCARE US, LLC:</p> <p>17 NATHAN B. REEDER, ESQ.</p> <p>18 PATRICK C. GALLAGHER, PhD, ESQ.</p> <p>19 FREDERICK R. BALL, ESQ.</p> <p>20 DUANE MORRIS, LLP</p> <p>21 30 South 17th Street</p> <p>22 Philadelphia, Pennsylvania 19103</p> <p>23 215-979-1164</p> <p>24 nbreeder@duanemorris.com</p> <p>pcgallagher@duanemorris.com</p> <p>frball@duanemorris.com</p>	<p style="text-align: right;">Page 5</p> <p>1 INDEX</p> <p>2 EXAMINATION PAGE</p> <p>3 PENG DONG</p> <p>4 BY MR. SLATER 8</p> <p>5</p> <p>6</p> <p>7 EXHIBITS</p> <p>8 NO. DESCRIPTION PAGE</p> <p>9 ZHP-191 Notice to Take Videotaped Oral Deposition..... 10</p> <p>10</p> <p>11 ZHP-192 Peng Dong's Curriculum Vitae.. 26</p> <p>12</p> <p>13 ZHP-193 Guideline for Genotoxic Impurity Evaluation, Bates ZHP01447235 through 7242..... 33</p> <p>14</p> <p>15 ZHP-194 Change Request Form, Chinese version, Bates ZHP00000161 through 214..... 64</p> <p>16</p> <p>17 ZHP-195 Change Request Form, English version, Bates ZHP01843066 through 3119..... 64</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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 DEPOSITION SUPPORT INDEX  
 - - -

Direction to Witness Not to Answer  
 PAGE LINE  
 None.

Request for Production of Documents  
 PAGE LINE  
 None.

Stipulations  
 PAGE LINE  
 None.

Questions Marked Highly Confidential  
 PAGE LINE  
 None.

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P R O C E E D I N G S

THE VIDEOGRAPHER: Okay. We are now on the record.

My name is Henry Marte. I'm a videographer on behalf of Golkow Litigation Services.

Today's date is March 29, 2021, and the time is 7:07 a.m.

This videotaped deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation.

The deponent today is Mr. Peng Dong.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All appearances are also noted on the stenographic record.

Will the court reporter please administer the oath to the witness.

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YANG SHAO, Interpreter,  
 having been duly sworn to translate the proceedings to the best of his ability, translated as follows:

PENG DONG,  
 having been duly affirmed to tell the truth, was examined and testified as follows:

EXAMINATION

BY MR. SLATER:

Q. Hello, Mr. Dong.

A. How are you?

Q. We're going to take your deposition now. Do you understand that's the purpose of this proceeding?

A. I understand. I will attend this deposition as a witness designated by the company.

Q. Please make sure that you tell the truth in answering every question.

A. I affirm that I will tell the truth.

Q. If you are asked a question you don't understand, please tell us, okay?

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A. All right.

Q. All right. If a lawyer objects to a question, please wait, and then you'll likely answer the question, but wait until you're told.

A. Okay.

Q. Most important, so that we get through this quickly, if I ask you a direct question, for example a yes-or-no question, please answer in a direct way.

A. I will tell the truth.

Q. Do you, in your -- rephrase. What language or languages do you communicate in at work?

A. Mandarin.

Q. Do you read or write English at all, whether at work or otherwise?

A. I do not write in English. As for the reading, I don't do much English reading.

Q. Can you understand English at all? I'm talking spoken.

THE VIDEOGRAPHER: Did the witness just freeze? He looks frozen.

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1 MR. BALL: He looks frozen.  
2 MR. SLATER: Go off.  
3 THE VIDEOGRAPHER: All right.  
4 The time is 7:13 a.m. Off the record.  
5 (Off the record.)  
6 THE VIDEOGRAPHER: All right.  
7 We are back on the record. The time  
8 is 7:15 a.m.  
9 BY MR. SLATER:  
10 Q. Before we disconnected, I  
11 asked, "Do you understand" -- I can't  
12 remember if this was answered. Rephrase.  
13 Do you understand spoken  
14 English at all?  
15 A. I would speak very little  
16 English, except for the greetings "hello" and  
17 "bye-bye."  
18 MR. SLATER: Let's mark the  
19 deposition notice, whatever exhibit  
20 we're up to.  
21 (Whereupon, Exhibit Number  
22 ZHP-191 was marked for  
23 identification.)  
24 MR. SLATER: Cheryll, if you

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1 could mark it, put it up on the  
2 screen, and then tell us what exhibit  
3 number it is, that would be great.  
4 MR. BALL: I object to the use  
5 of this document without a  
6 translation.  
7 To the degree that Dr. Shao can  
8 translate it for Mr. Peng, I would  
9 instruct Mr. Peng to go ahead and  
10 answer, or ask Dr. Shao to translate  
11 whatever he needs to translate to  
12 fully understand the document.  
13 THE WITNESS: I need the  
14 interpreter to translate the whole  
15 document.  
16 MR. SLATER: Yeah, we're not  
17 going to do that. I'm going to ask my  
18 questions, and I'm going to continue.  
19 Mr. Ball, if you want to tell  
20 him not to answer questions, you can  
21 instruct him not to answer. You don't  
22 even know what I'm going to ask.  
23 But I'm not going to sit here  
24 while the whole deposition notice is

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1 translated when it's not necessary for  
2 my questions.  
3 MR. BALL: And we could go off  
4 the record and talk about this, or you  
5 can listen to the objection that I  
6 made.  
7 MR. SLATER: I heard your  
8 objection. He just asked to read the  
9 whole document. We're not going down  
10 that road.  
11 MR. BALL: Mr. Slater, you  
12 could have provided a translated  
13 document. You chose not to. That's  
14 really not my problem that you chose  
15 not to.  
16 MR. SLATER: All right. Let's  
17 continue.  
18 BY MR. SLATER:  
19 Q. Mr. Peng -- Mr. Dong, were you  
20 aware that a deposition notice applies to  
21 this deposition?  
22 A. I'm not quite sure.  
23 Q. Did anybody ever translate the  
24 deposition notice for you, to your knowledge,

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1 and tell you what it said?  
2 A. To the best of my recollection,  
3 no.  
4 Q. Do you know the topics on which  
5 you're supposed to be testifying tonight?  
6 A. I have some knowledge on those  
7 topics.  
8 Q. What do you think the topics at  
9 this deposition are?  
10 A. For that I need to read the  
11 original document.  
12 Q. If you don't know what the  
13 document says, why do you need me to read it  
14 to you?  
15 MR. BALL: Objection.  
16 A. There are several topics where  
17 I need to testify on. However, it is  
18 impossible for me to recite all those topics  
19 one by one.  
20 BY MR. SLATER:  
21 Q. Recite one for me, please.  
22 A. To the best of my recollection,  
23 as a corporate witness, I am supposed to  
24 testify on the topic of valsartan changes.

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1 Q. When you say "valsartan  
2 changes," do you mean valsartan process  
3 changes?  
4 MR. BALL: Objection to form.  
5 A. I would like the opposing  
6 counsel to indicate the time frame when you  
7 say "valsartan process changes."  
8 BY MR. SLATER:  
9 Q. You said you're testifying on  
10 valsartan changes. I asked you if you meant  
11 valsartan process changes. It's a yes-or-no  
12 question.  
13 MR. BALL: Objection to form.  
14 A. My understanding regarding  
15 valsartan changes might be different from the  
16 opposing counsel's understanding of valsartan  
17 changes.  
18 If I am not provided with the  
19 real intention and a clear question from the  
20 opposing counsel, then it is impossible for  
21 me to provide an accurate response to his  
22 question.  
23 BY MR. SLATER:  
24 Q. When you said that you're here

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1 to testify on valsartan changes, what did you  
2 mean by that?  
3 A. When I said "valsartan  
4 changes," I was referring to the questions  
5 that I received or the topics I became aware  
6 of that I need to testify as a corporate  
7 witness.  
8 In order to provide an accurate  
9 response, either I would be presented with  
10 the original document or the interpreter  
11 could translate the document for me.  
12 MR. SLATER: Counsel, I'm just  
13 going to ask you to instruct your  
14 witness to actually give responsive  
15 answers, because this is not  
16 responsive. It's canned stuff. And  
17 I'm not going to have my time taken by  
18 these kinds of answers.  
19 MR. BALL: Adam, he's giving  
20 responsive answers. I'm not going to  
21 instruct him to do anything.  
22 MR. SLATER: I reserve my right  
23 to seek sanctions for this time.  
24 MR. BALL: Fine.

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1 And, Adam, as you know, that's  
2 inappropriate to threaten sanctions.  
3 MR. SLATER: I didn't threaten.  
4 I said --  
5 MR. BALL: And if you -- Adam,  
6 let me finish, please.  
7 If you do it again, if you  
8 continue to do that, we will consider  
9 filing a counter motion if you do.  
10 You have the document in front  
11 of you. You can show him the  
12 questions. They can be translated.  
13 You chose not to do that. That's  
14 really not my problem, again.  
15 And if you want to go off the  
16 record and not take up your time and  
17 discuss these issues, I'm happy to do  
18 that.  
19 MR. SLATER: We'll just make a  
20 record. It's fine. Let your witness  
21 keep answering this way. He's  
22 obviously doing it at instruction of  
23 counsel, right? I mean, you're in  
24 charge, right?

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1 MR. BALL: Objection. Calls  
2 for attorney/client privilege.  
3 MR. SLATER: Okay.  
4 BY MR. SLATER:  
5 Q. Did you prepare for this  
6 deposition?  
7 A. I did some preparation.  
8 Q. Who did you prepare for this  
9 deposition with?  
10 A. I reviewed some documents.  
11 Q. I asked you who you prepared --  
12 rephrase.  
13 I asked you who you prepared  
14 with. What people did you prepare for the  
15 deposition with?  
16 A. I did collect some internal  
17 information from my colleagues at ZHP.  
18 Q. Who?  
19 A. There are a quite a few. Would  
20 you like to know the names of each of them?  
21 Q. Yes. List the names to the  
22 best of your ability, please.  
23 A. Since I was not involved in any  
24 work related to valsartan before 2014, I did

<p style="text-align: right;">Page 18</p> <p>1 approach some people to gather information                  2 about valsartan.                  3 Q. I asked you to list the names                  4 of the people. Can you just list the names                  5 for me, please?                  6 A. What do you mean by listing                  7 their names? Do you want me to orally                  8 repeat?                  9 Q. Yes. I would like you to tell                  10 me their names. This is a sworn oral                  11 deposition, so please speak the names.                  12 MR. BALL: Objection.                  13 Harassment.                  14 MR. SLATER: Harassment because                  15 I -- wait a second. Harassment? He                  16 said, "Would you like me to list the                  17 names" three questions ago. I said                  18 "Yes," and now he's acting like he                  19 doesn't understand what I'm asking.                  20 Counsel, it's like five or six                  21 times he's done this already. It's                  22 outrageous.                  23 MR. BALL: Please go off the                  24 record for a second.</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. Did you speak to any lawyers to                  2 prepare for the deposition?                  3 A. I did talk with attorneys in                  4 the past.                  5 Q. To prepare for this deposition?                  6 A. We did have some conversation.                  7 Q. Which lawyers did you speak to?                  8 A. For example, this attorney from                  9 our side.                  10 Q. Mr. Dong, can you tell me the                  11 name of each lawyer that helped prepare you                  12 for this deposition, please?                  13 A. I did have some conversation                  14 with the attorneys.                  15 Q. What are their names?                  16 A. My English skill is poor, so if                  17 I pronounce correctly, I believe his name is                  18 Rick.                  19 Q. Who else?                  20 A. I'm afraid I cannot pronounce                  21 the name of that person.                  22 Q. Tell me the name of any Chinese                  23 lawyers who helped to prepare you for the                  24 deposition, please.</p>
<p style="text-align: right;">Page 19</p> <p>1 THE VIDEOGRAPHER: All right.                  2 The time is 7:32 a.m. Off the record.                  3 (Off the record discussion.)                  4 THE VIDEOGRAPHER: The time is                  5 7:34 a.m. Back on the record.                  6 BY MR. SLATER:                  7 Q. Please tell me the name of each                  8 person you spoke with to prepare for this                  9 deposition.                  10 A. Every name? There are many                  11 names. I'm afraid I cannot recall each and                  12 every name.                  13 Q. List the ones you can recall,                  14 please, speaking them to me, please.                  15 A. Let me see.                  16 THE INTERPRETER: The                  17 interpreter would like to clarify with                  18 the witness.                  19 A. For example, Yueling Hu,                  20 spelled as Y-U-E-L-I-N-G, last name H-U.                  21 Q. That's the only name you can                  22 remember?                  23 A. That's all I can recall as of                  24 now.</p>	<p style="text-align: right;">Page 21</p> <p>1 MR. BALL: Objection to form.                  2 A. What do you mean by any Chinese                  3 attorneys?                  4 BY MR. SLATER:                  5 Q. An attorney from China whose                  6 name you can remember.                  7 A. To the best of my recollection,                  8 I never had a conversation with so-called                  9 Chinese attorneys.                  10 Q. So is the attorney who you                  11 said, Rick, the lawyer who is on this                  12 deposition with us, Mr. Rick Ball?                  13 A. That is correct.                  14 Q. How many times did you speak to                  15 him to prepare for the deposition?                  16 A. We did talk to each other for a                  17 few times. However, I do not recall the                  18 exact time, or times.                  19 Q. For how long did you speak to                  20 Mr. Ball preparing for the deposition?                  21 A. What do you mean by -- how long                  22 is the conversation?                  23 Q. How much time did you speak to                  24 him for over the course of your discussions</p>



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1 with him preparing for the deposition?  
 2 MR. BALL: Objection to form.  
 3 A. I did have some discussion with  
 4 him. However, I would like some  
 5 clarification from the plaintiffs' attorney.  
 6 Do you mean the total length of  
 7 time for the discussion between us?  
 8 BY MR. SLATER:  
 9 Q. Yes.  
 10 A. I don't recall.  
 11 Q. Was it more than an hour?  
 12 A. My conversation with that  
 13 attorney took more than an hour.  
 14 Q. More than five hours?  
 15 A. Well, maybe.  
 16 Q. Did you bring any documents to  
 17 give to me as part of this deposition?  
 18 A. I don't understand your  
 19 question. What do you mean by bringing any  
 20 document to you?  
 21 Q. Are you producing any documents  
 22 in connection with the deposition?  
 23 MR. BALL: Objection. Vague.  
 24 A. I don't understand what you

Page 23

1 mean.  
 2 BY MR. SLATER:  
 3 Q. Okay. Do you know what a  
 4 document is?  
 5 A. There are many types of  
 6 documents.  
 7 Q. Great. Are you producing any  
 8 types of documents as part of this  
 9 deposition? Are you bringing anything --  
 10 rephrase.  
 11 Are there any documents that  
 12 you're producing as part of this deposition,  
 13 any type?  
 14 MR. BALL: Objection to form.  
 15 A. I don't understand the word  
 16 "producing."  
 17 BY MR. SLATER:  
 18 Q. At your work, do you  
 19 communicate with your coworkers by e-mail?  
 20 A. Yes.  
 21 Q. Has that been true since you  
 22 first started to work for ZHP?  
 23 A. Let me see. It has been a long  
 24 time between now and my first day at ZHP.

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1 To the best of my recollection,  
 2 at that time I was at a very junior level,  
 3 and I was not authorized to apply for an  
 4 e-mail address.  
 5 Q. Are you saying you didn't use  
 6 e-mail when you first started working at ZHP?  
 7 A. That is correct.  
 8 Q. When did you first get e-mail  
 9 at your company?  
 10 Let me ask it differently.  
 11 Withdrawn. New question.  
 12 When did you first have an  
 13 e-mail address at your work at ZHP?  
 14 A. I believe it was a long time  
 15 ago that I started to have my work e-mail at  
 16 ZHP. I do not recall.  
 17 Q. Did you have e-mail at ZHP  
 18 before December 12, 2017?  
 19 A. Yes.  
 20 Q. Did you send and receive  
 21 e-mails before December 12, 2017 in your work  
 22 at ZHP?  
 23 A. From that date or since that  
 24 date, I have been receiving and sending

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1 e-mails using my work e-mail address in the  
 2 course of my employment.  
 3 Q. I asked if you did so before  
 4 December 12, 2017. Please answer that  
 5 question.  
 6 A. Yes.  
 7 Q. Do you know when you first sent  
 8 or received e-mails in your work at ZHP?  
 9 A. I don't recall, since it was  
 10 long time ago.  
 11 MR. SLATER: Cheryll, I want to  
 12 put up the CV only if it was produced  
 13 by ZHP to us. So can you tell me, was  
 14 it produced by ZHP, or did we get it  
 15 from somewhere else? Did we get it  
 16 from them, or did we get it from  
 17 somewhere else?  
 18 I'm asking my associate. It's  
 19 not a question.  
 20 MS. CALDERON: We received the  
 21 CV from counsel.  
 22 MR. SLATER: Great. Put it on  
 23 the screen. Next exhibit, 192.  
 24 ///



<p style="text-align: right;">Page 26</p> <p>1 (Whereupon, Exhibit Number                  2 ZHP-192 was marked for                  3 identification.)                  4 BY MR. SLATER:                  5 Q. Mr. Dong, in front of us is the                  6 CV -- rephrase.                  7 Mr. Dong, you can't read the                  8 document in front of you, right?                  9 A. Well, I am only familiar with a                  10 few words in this document.                  11 MR. SLATER: For the record,                  12 this document was produced to us by                  13 counsel as Mr. Dong's CV. Just making                  14 that record.                  15 Q. Mr. Dong, do you have a CV in                  16 the Chinese or Mandarin language that you'd                  17 be able to read completely?                  18 A. To the best of my recollection,                  19 I do not have my CV in Chinese. And this                  20 version was actually written by a colleague                  21 of mine when I told him the content.                  22 Q. Do you know whether it's                  23 accurate or not?                  24 A. What do you mean by this</p>	<p style="text-align: right;">Page 28</p> <p>1 technical department at Chuannan facility of                  2 ZHP.                  3 Q. What is the responsibility of                  4 the technical department?                  5 A. Are you referring to the                  6 responsibilities of my position or the whole                  7 department when you said "the responsibility                  8 of the technical department"?                  9 Q. When I said -- rephrase.                  10 The technical department.                  11 That's why I asked the question that way.                  12 Hold on. Hold on.                  13 The technical department, the                  14 whole department.                  15 A. The responsibility of the                  16 technical department covers two areas. One                  17 is management of technology, or technical                  18 management. The other area is improvement of                  19 the process or processes.                  20 Q. What processes are you                  21 referring to?                  22 A. I did not say "processes," so I                  23 don't understand the question.                  24 Q. That was the translation I was</p>
<p style="text-align: right;">Page 27</p> <p>1 document accurate or not?                  2 Q. Is the information correct?                  3 A. Which specific entry are you                  4 referring to?                  5 Q. The whole thing.                  6 MR. BALL: Again, I'm going to                  7 object to the use of this document.                  8 If you want to translate                  9 certain sections and have Dr. Shao                  10 translate sections of it, he can                  11 answer questions about it. Just what                  12 he just told you, Adam.                  13 BY MR. SLATER:                  14 Q. I'm waiting for an answer.                  15 A. Excuse me. What was the                  16 original question of the plaintiffs'                  17 attorney?                  18 Q. What department do you work in?                  19 MR. BALL: Object to form.                  20 A. When you say do I work, do you                  21 mean my current job position?                  22 BY MR. SLATER:                  23 Q. Yes.                  24 A. Right now I work in the</p>	<p style="text-align: right;">Page 29</p> <p>1 given. You said "process or processes,"                  2 so...                  3 THE INTERPRETER: The                  4 interpreter clarifies that in Chinese                  5 there is no singular or plural form.                  6 So, to be complete, the interpreter                  7 choose to use both the singular or the                  8 plural form, just in case.                  9 Q. Okay. I'll ask a new question.                  10 What process are you referring                  11 to?                  12 A. The responsibility of the                  13 technical department is to improve and                  14 upgrade the manufacturing process for the                  15 products under our management.                  16 MR. BALL: Please don't                  17 translate this.                  18 Adam, are you asking him in his                  19 capacity as a 30(b)(6) witness? His                  20 individual capacity?                  21 Can I finish, please? I                  22 thought the deposition started with                  23 the 30(b)(6) questions.                  24 MR. SLATER: I think I'm</p>

<p style="text-align: right;">Page 30</p> <p>1 allowed to find out who the witness is                  2 and what department he works in as                  3 part of the 30(b)(6).                  4 MR. BALL: I just want to make                  5 sure that these -- then I'm going to                  6 object.                  7 And I'm just going to put on                  8 the record these answers, I believe,                  9 are outside the scope of the 30(b)(6)                  10 and don't bind the company.                  11 Go ahead.                  12 MR. SLATER: I'm sorry. You                  13 think that me asking the 30(b)(6)                  14 witness what his department does is                  15 outside the scope of the deposition?                  16 MR. BALL: Yes, I do believe                  17 that. Outside the scope of the                  18 30(b)(6). You can ask him in his                  19 individual capacity, and that's fine.                  20 He's not binding the company.                  21 MR. SLATER: That's great. We                  22 disagree.                  23 BY MR. SLATER:                  24 Q. What are your responsibilities</p>	<p style="text-align: right;">Page 32</p> <p>1 A. In Chinese, literally it's                  2 translated as director assistant.                  3 MR. SLATER: I'm going to go                  4 into a new area now. I don't know                  5 when you need your first break. I                  6 know that you need breaks                  7 periodically, so I just...                  8 THE INTERPRETER: The                  9 interpreter would request a brief                  10 break in order to start the realtime.                  11 MR. SLATER: Great. Let's go                  12 off.                  13 MR. BALL: Okay. Hold on, hold                  14 on.                  15 Dong, do you have -- is your                  16 breakfast there? Do we need to take                  17 15 minutes, or are we just going to                  18 take 10?                  19 MR. SLATER: Go off the video.                  20 We're not using my time to get his                  21 breakfast menu, please.                  22 THE VIDEOGRAPHER: All right.                  23 The time is 8:08 a.m. Going off the                  24 record.</p>
<p style="text-align: right;">Page 31</p> <p>1 in your position?                  2 A. My own responsibilities would                  3 cover three areas.                  4 First, management of the                  5 department. Second, to organize my                  6 subsidiaries to conduct technical management.                  7 The third one, participation in organization                  8 of the improvement of manufacturing process                  9 for the product we manage.                  10 Q. Your current title is deputy                  11 director of the technical department, is that                  12 correct?                  13 A. That is correct.                  14 Q. When did you get that title?                  15 What day?                  16 A. I do not recall the specific                  17 month and day.                  18 Q. Tell me what you do recall.                  19 A. To the best of my recollection,                  20 I was promoted to that title in early 2018,                  21 but I do not recall the specific month and                  22 date.                  23 Q. Your prior title was assistant                  24 director, correct?</p>	<p style="text-align: right;">Page 33</p> <p>1 (Whereupon, a recess was                  2 taken.)                  3 THE VIDEOGRAPHER: The time is                  4 8:24 a.m. Back on the record.                  5 (Whereupon, Exhibit Number                  6 ZHP-193 was marked for                  7 identification.)                  8 BY MR. SLATER:                  9 Q. Do you see this exhibit in                  10 front of you titled "Guideline for Genotoxic                  11 Impurity Evaluation"?                  12 A. I see it.                  13 Q. Look at Section 2, please.                  14 This states in part, "All intermediates and                  15 APIs produced under GMP conditions must be                  16 identified for genotoxic impurities."                  17 Do you see that?                  18 A. I see it. The document does                  19 state so.                  20 Q. Identification of genotoxic                  21 impurities is part of the risk assessment                  22 evaluation, correct?                  23 A. Per the requirements of ICH, we                  24 would confirm the quality specifications of</p>

<p style="text-align: right;">Page 34</p> <p>1 API.</p> <p>2 Q. This applies to valsartan,</p> <p>3 correct?</p> <p>4 Let me reask the question.</p> <p>5 Hang on. Let me reask the question.</p> <p>6 What you just stated would</p> <p>7 apply to valsartan, correct?</p> <p>8 A. For API products, including</p> <p>9 valsartan API, we would confirm the quality</p> <p>10 specifications per the requirements of ICH.</p> <p>11 Q. Part of evaluating -- rephrase.</p> <p>12 Part of this process includes</p> <p>13 identifying all genotoxic impurities,</p> <p>14 correct?</p> <p>15 A. What do you mean by "part of</p> <p>16 this process"?</p> <p>17 Q. The GMP process to ensure the</p> <p>18 product meets quality requirements.</p> <p>19 A. Can you repeat your question by</p> <p>20 putting what you just said? I'm sorry.</p> <p>21 Q. No.</p> <p>22 Let's go to Section 4.2.1. In</p> <p>23 part, this says, "Sources of genotoxic</p> <p>24 substances include raw materials, reagents,</p>	<p style="text-align: right;">Page 36</p> <p>1 As for those ICH requirements</p> <p>2 and SOPs, they had certain effective period</p> <p>3 of time, and that would start with an</p> <p>4 effective date.</p> <p>5 MR. SLATER: Move to strike.</p> <p>6 Q. It's a very simple question.</p> <p>7 The information I read to you in</p> <p>8 Section 4.2.1, did ZHP know the sources of</p> <p>9 the genotoxic substances when it first</p> <p>10 started manufacturing valsartan? Yes or no.</p> <p>11 Did it know that list or not?</p> <p>12 A. Section 4.2.1 is indeed</p> <p>13 included in this document. However, I need</p> <p>14 to know the effective date of this document.</p> <p>15 In addition, we conducted our</p> <p>16 work in developing the manufacturing process</p> <p>17 of valsartan based on the requirements of ICH</p> <p>18 then, as well as the internal SOP regulations</p> <p>19 then.</p> <p>20 MR. SLATER: Move to strike.</p> <p>21 Q. I'm going to ask you a question</p> <p>22 not referring to this document to try to get</p> <p>23 you to answer responsively.</p> <p>24 From the time ZHP began to</p>
<p style="text-align: right;">Page 35</p> <p>1 solvents, intermediates, and by-products,"</p> <p>2 correct?</p> <p>3 A. The document does say so in</p> <p>4 Chinese.</p> <p>5 Q. And your company knew that from</p> <p>6 the time it began to manufacture valsartan,</p> <p>7 correct?</p> <p>8 A. I believe this document should</p> <p>9 have an effective date. I'm sorry, I missed</p> <p>10 the effective date.</p> <p>11 Q. My question --</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 Q. What I just read in 4.2.1 your</p> <p>14 company has known from the first day it ever</p> <p>15 manufactured valsartan, correct?</p> <p>16 A. I need to know the effective</p> <p>17 date of this document.</p> <p>18 Q. Do you know if your company</p> <p>19 knew the sources of genotoxic substances when</p> <p>20 it first started manufacturing valsartan?</p> <p>21 Yes or no.</p> <p>22 A. We conducted our work based on</p> <p>23 the requirements of ICH as well as the</p> <p>24 regulations of our internal SOPs.</p>	<p style="text-align: right;">Page 37</p> <p>1 manufacture valsartan, did it know that the</p> <p>2 sources of genotoxic substances included raw</p> <p>3 materials, reagents, solvents, intermediates,</p> <p>4 and by-products? Yes or no.</p> <p>5 A. When ZHP first started to</p> <p>6 manufacture valsartan, they conducted the</p> <p>7 work based on the requirement of ICH then, as</p> <p>8 well as the regulations of the internal SOP</p> <p>9 then.</p> <p>10 When I mentioned ICH and SOP, I</p> <p>11 was referring to the documents then.</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 Q. Can you just answer with a yes</p> <p>14 or no, please, the actual question I asked?</p> <p>15 A. What was your original question</p> <p>16 again?</p> <p>17 MR. SLATER: Go off the record.</p> <p>18 THE VIDEOGRAPHER: All right.</p> <p>19 The time is 8:40 a.m. Off the record.</p> <p>20 (Off the record discussion.)</p> <p>21 THE VIDEOGRAPHER: The time is</p> <p>22 8:41 a.m. Back on the record.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. I am told that this document</p>

<p style="text-align: right;">Page 38</p> <p>1 was created in 2011.</p> <p>2 MR. BALL: Objection to form.</p> <p>3 MR. SLATER: What's the</p> <p>4 objection?</p> <p>5 MR. BALL: Foundation. You</p> <p>6 were told, Adam?</p> <p>7 MR. SLATER: You're really</p> <p>8 having a fun time over there, Rick,</p> <p>9 aren't you?</p> <p>10 MR. BALL: You know, Adam, I'm</p> <p>11 going to make my objections. You</p> <p>12 asked me what my objection was, and I</p> <p>13 just told you.</p> <p>14 MR. SLATER: I hadn't even</p> <p>15 finished my sentence, but --</p> <p>16 MR. BALL: Okay.</p> <p>17 MR. SLATER: -- keep having a</p> <p>18 grand time over there. It's fine.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. I'm told that the metadata for</p> <p>21 this document shows that it was created in</p> <p>22 2011. Do you know whether that's correct or</p> <p>23 not?</p> <p>24 MR. BALL: Objection to form.</p>	<p style="text-align: right;">Page 40</p> <p>1 document before, what time frame are you</p> <p>2 referring to?</p> <p>3 Q. Ever in your life before today.</p> <p>4 A. To the best of my recollection,</p> <p>5 I have seen this document before. It seems</p> <p>6 so.</p> <p>7 Q. Have you ever used this</p> <p>8 document in your work?</p> <p>9 A. In the course of my employment,</p> <p>10 we conducted our work based on the</p> <p>11 requirements of ICH and SOP then.</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 MR. BALL: Oppose the motion.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Mr. Dong, did I ask you about</p> <p>16 ICH? No, I didn't.</p> <p>17 Did I ask you about any other</p> <p>18 SOPs? No, I didn't.</p> <p>19 I would appreciate, like I</p> <p>20 asked you up front, to be courteous and</p> <p>21 comply with your obligations under the United</p> <p>22 States Federal Rules of Civil Procedure and</p> <p>23 answer the questions I actually ask you. I</p> <p>24 would really appreciate that. It would make</p>
<p style="text-align: right;">Page 39</p> <p>1 A. Can you show me the time? I</p> <p>2 cannot find that time in this document.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. I asked you if you know.</p> <p>5 Either the answer is yes or no.</p> <p>6 MR. BALL: Objection to form.</p> <p>7 A. Judging from what is shown to</p> <p>8 me on the screen, it is impossible for me to</p> <p>9 tell when this document was created, nor</p> <p>10 could I tell that -- what the effective date</p> <p>11 of this document is.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Have you ever seen this</p> <p>14 document --</p> <p>15 MR. SLATER: Move to strike.</p> <p>16 Q. Have you ever seen this</p> <p>17 document --</p> <p>18 MR. BALL: Oppose the motion.</p> <p>19 MR. SLATER: I'm going to start</p> <p>20 over.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Have you ever seen this</p> <p>23 document before?</p> <p>24 A. When you said have I seen this</p>	<p style="text-align: right;">Page 41</p> <p>1 things go a lot smoother for everybody.</p> <p>2 MR. BALL: Objection to form.</p> <p>3 I don't even know if that was a</p> <p>4 question.</p> <p>5 MR. SLATER: No. It was a</p> <p>6 request for the witness to actually</p> <p>7 make some minimal effort to be</p> <p>8 responsive.</p> <p>9 MR. BALL: Objection.</p> <p>10 Harassment.</p> <p>11 Go ahead and translate it.</p> <p>12 A. I will tell you the truth.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Look at Section 4.2.3. It says</p> <p>15 in part, "After product pilot, genotoxic</p> <p>16 impurities should be preliminarily determined</p> <p>17 and included in the development report."</p> <p>18 Correct?</p> <p>19 MR. BALL: Objection to form.</p> <p>20 A. According to this document, it</p> <p>21 says in this section, "After the research and</p> <p>22 development of the product pilot, genotoxic</p> <p>23 impurities should be preliminarily determined</p> <p>24 and included in the development report."</p>

<p style="text-align: right;">Page 42</p> <p>1 That's what it says in Chinese.                  2 BY MR. SLATER:                  3 Q. Look at 4.2.4. That says, "The                  4 identification of genotoxic impurities should                  5 include confirmed structure of genotoxic                  6 impurities and confirm analysis method and                  7 residual limit of the impurity." Correct?                  8 MR. BALL: Objection to form.                  9 A. According to this document, the                  10 Chinese statement does say so in                  11 Section 4.2.4.                  12 BY MR. SLATER:                  13 Q. Let's go to Section 4.3.1.                  14 This section says, "The technical department                  15 organizes relevant departments to evaluate                  16 all raw materials, reagents, solvents,                  17 intermediates, and by-products of the product                  18 and evaluate whether they contain genotoxic                  19 substances." Correct?                  20 MR. BALL: Objection to form.                  21 A. In Section 4.3.1 of this                  22 document, the Chinese version says, "The                  23 technical department should organize relevant                  24 departments to evaluate all raw materials,</p>	<p style="text-align: right;">Page 44</p> <p>1 your technical department, the one you work                  2 in, correct?                  3 MR. BALL: Objection to form.                  4 BY MR. SLATER:                  5 Q. Let me stop. Let me stop. Let                  6 me withdraw the question.                  7 There's a technical department                  8 for the Chuannan facility where the valsartan                  9 API was manufactured, correct?                  10 MR. BALL: Objection to form.                  11 A. There is a technical department                  12 at the Chuannan facility of ZHP.                  13 BY MR. SLATER:                  14 Q. This guideline applies to that                  15 technical department, correct?                  16 MR. BALL: Objection to form.                  17 A. Are you referring to this SOP                  18 by "this guideline"?                  19 BY MR. SLATER:                  20 Q. Yes.                  21 A. Can you repeat the pending                  22 question? I'm sorry.                  23 Q. This guideline that is on the                  24 screen applies to the technical department in</p>
<p style="text-align: right;">Page 43</p> <p>1 reagents, solvents, intermediates, and                  2 by-products of the product, and evaluate                  3 whether there are any genotoxic substances in                  4 them." That's what the Chinese says.                  5 BY MR. SLATER:                  6 Q. The technical department is the                  7 department that you work in, correct?                  8 MR. BALL: Objection to form.                  9 A. Do you mean the technical                  10 department described in this document when                  11 you say "technical department"?                  12 BY MR. SLATER:                  13 Q. Is the technical department                  14 referenced in 4.3.1 the department you work                  15 in?                  16 MR. BALL: Objection to form.                  17 A. The technical departments                  18 referred in this document under Section 4.3.1                  19 refer to all the technical departments in                  20 ZHP's facilities. My department is only one                  21 of them.                  22 BY MR. SLATER:                  23 Q. This instruction to the                  24 technical departments would also apply to</p>	<p style="text-align: right;">Page 45</p> <p>1 Chuannan, correct?                  2 MR. BALL: Objection -- sorry.                  3 Objection to form.                  4 A. The technical department in                  5 Chuannan should conduct their work based on                  6 the current SOP.                  7 BY MR. SLATER:                  8 Q. When Section 4.3.1 refers to                  9 the "technical departments" plural, that                  10 includes the technical department at                  11 Chuannan, correct?                  12 MR. BALL: Objection to form.                  13 A. After this SOP became                  14 effective, all the technical departments                  15 referred to under Section 4.1 point --                  16 THE INTERPRETER: The                  17 interpreter's correction.                  18 A. -- under Section 4.3.1,                  19 including the technical department in                  20 Chuannan, need to conduct their work based on                  21 the effective SOP at that time.                  22 BY MR. SLATER:                  23 Q. Look at 4.4.1. The first part                  24 says, "Genotoxic substances are potentially</p>



<p style="text-align: right;">Page 46</p> <p>1 destructive to DNA at any intake level, and                  2 this damage may lead to tumors." Correct?                  3 It says that in part, correct?                  4 MR. BALL: Objection to form.                  5 A. One sentence under                  6 Section 4.4.1 of this document does say that                  7 "Genotoxic substances are potentially                  8 destructive to DNA at any intake level, and                  9 this damage may lead to tumors."                  10 This sentence is only within                  11 this paragraph under Section 4.4.1.                  12 BY MR. SLATER:                  13 Q. Go to Section 4.4.11. This                  14 indicates that "Genotoxic impurities and                  15 their residual limits as found by the company                  16 are found in Appendix A." Correct?                  17 MR. BALL: Objection to form.                  18 A. In this document under                  19 Section 4.4.11, the sentence in Chinese does                  20 say, "The genotoxic impurities and their                  21 residual limits as determined by the company                  22 are found in Appendix A."                  23 In addition, could you please                  24 scroll up this document a little bit? It</p>	<p style="text-align: right;">Page 48</p> <p>1 your question. Are you asking me whether I'm                  2 done with responding to the previous                  3 question?                  4 BY MR. SLATER:                  5 Q. Because it says "002," that                  6 means it's the second version. You know how                  7 your documents are written in your company,                  8 right?                  9 MR. BALL: Objection to form.                  10 Harassment.                  11 A. I need to review the whole                  12 document before responding to the opposing                  13 counsel's question.                  14 BY MR. SLATER:                  15 Q. We can go off the record if you                  16 want to read the whole document.                  17 MR. BALL: No, we won't. He                  18 can read it on the record. He will                  19 take the time, your time, to do that.                  20 MR. SLATER: I'm sorry, but                  21 we're not going to. I'm not going to                  22 sit while he reads the whole document.                  23 I don't know what he's reading for.                  24 The date of the document is not on it,</p>
<p style="text-align: right;">Page 47</p> <p>1 makes me feel tired when I have to look down                  2 at this paragraph. I'm sorry.                  3 MR. SLATER: I don't                  4 understand. Move to strike the last                  5 part.                  6 MR. BALL: Oppose the motion.                  7 BY MR. SLATER:                  8 Q. Mr. Dong, if you look in the                  9 top left, it says number "API-R&amp;D-002."                  10 Do you see that?                  11 MR. BALL: Objection to form.                  12 A. As shown on the screen, on this                  13 document at the upper left corner, there is                  14 indeed a number "API-R&amp;D-002."                  15 BY MR. SLATER:                  16 Q. By -- rephrase.                  17 Since it says "002," this is                  18 version 2 of this guideline, correct?                  19 MR. BALL: Objection to form.                  20 A. This is a document number.                  21 BY MR. SLATER:                  22 Q. That's your answer?                  23 MR. BALL: Objection to form.                  24 A. I'm sorry. I don't understand</p>	<p style="text-align: right;">Page 49</p> <p>1 so I don't know what he's looking for.                  2 MR. BALL: Well, then, I don't                  3 know what he's looking for either.                  4 Why don't you ask him. But we're not                  5 going off the record.                  6 MR. SLATER: This isn't how                  7 we're going to do this.                  8 MR. BALL: We're not going off                  9 the record.                  10 MR. SLATER: I've got a                  11 different way of asking it, Mr. Ball.                  12 BY MR. SLATER:                  13 Q. Mr. Dong, do you know if this                  14 is the only version of this document or not?                  15 Yes or no. It's a simple yes-or-no question.                  16 MR. BALL: Objection to form.                  17 A. In order to provide an accurate                  18 answer, I need to review the whole document.                  19 BY MR. SLATER:                  20 Q. Okay. Well, you can do that on                  21 your own time.                  22 MR. SLATER: Let's go to                  23 Appendix A. Perfect.                  24 Q. This is Appendix A, correct?</p>



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1 MR. BALL: Objection to form.  
2 A. It says here after "Attachment  
3 A," "List of genotoxic impurities by ZHP."  
4 That's what it says.  
5 BY MR. SLATER:  
6 Q. In line 7, line 9, and line 10,  
7 the product in the right-hand column is  
8 valsartan, correct?  
9 MR. BALL: Objection to form.  
10 A. In line 7, line 9, and line 10  
11 of this document, in the right-hand column,  
12 the product in Chinese is valsartan.  
13 BY MR. SLATER:  
14 Q. The left-hand column is the  
15 list of impurities.  
16 Do you see that?  
17 MR. BALL: Objection to form.  
18 MR. SLATER: What's your  
19 objection, Counsel?  
20 MR. BALL: My objection is, why  
21 don't you -- never mind. I don't --  
22 my objection is that's vague, first  
23 off.  
24 MR. SLATER: Are you just

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1 objecting to form to --  
2 MR. BALL: You haven't laid a  
3 foundation. You haven't laid a  
4 foundation.  
5 MR. SLATER: Okay. I think  
6 you're objecting to form every time  
7 you can't read the language, just  
8 to -- just for the heck of it. I  
9 mean --  
10 MR. BALL: As far as I know,  
11 Adam, you don't read Chinese.  
12 MR. SLATER: No, I don't.  
13 MR. BALL: So I'm not relying  
14 on your translation of it.  
15 MR. SLATER: Okay. So you're  
16 objecting to the form in case the  
17 translation is wrong?  
18 MR. BALL: I'm objecting to  
19 the -- I'm objecting that you did not  
20 lay a foundation for what the  
21 left-hand column says.  
22 MR. SLATER: Okay. That's what  
23 that question was, actually.  
24 MR. BALL: No, it wasn't. It

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1 was "The left-hand column  
2 says...correct?" Which is you  
3 translating the left-hand column and  
4 asking my witness if that's what it  
5 says.  
6 MR. SLATER: Yes. Right. And  
7 then if it's -- and then -- all right.  
8 And then if he's -- all right.  
9 Whatever. You know what? Nice.  
10 Good.  
11 BY MR. SLATER:  
12 Q. The left-hand column, the title  
13 is "List of impurities," correct?  
14 MR. BALL: Objection to form.  
15 A. In this list, the second column  
16 at the top says in Chinese "Names of the  
17 impurities of genotoxicity." That's what it  
18 says in Chinese.  
19 BY MR. SLATER:  
20 Q. Next to number 7 in that  
21 column, it says "azide," correct?  
22 MR. BALL: Objection to form.  
23 BY MR. SLATER:  
24 Q. I'll ask it differently.

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1 How about we'll do it this way.  
2 On line 7 in the impurities column that you  
3 just read the title for, what is the impurity  
4 that's listed there?  
5 A. In this table under the second  
6 column in line 7, it says "azide" here.  
7 Q. What does it say in line 9 in  
8 that column for valsartan?  
9 A. What do you mean by "line 9 in  
10 that column for valsartan"? Are you asking  
11 me to read aloud the content of the whole  
12 line 9?  
13 Q. In the column that's titled  
14 "Names of the impurities," next to the number  
15 9, what does it say for the impurity?  
16 A. In the table as shown on the  
17 screen, under column 2 in line 9, it says  
18 "Bromo OBTN."  
19 Q. What does it say directly  
20 beneath that on line 10 in that column?  
21 A. In the table shown on the  
22 screen, under column 2 in line 10, it says  
23 "Bromo OBTN tetrazole."  
24 Q. Let's go to the prior page.

<p style="text-align: right;">Page 54</p> <p>1 Looking at the top of this</p> <p>2 page, does this tell you whether this is the</p> <p>3 first version of this guideline or not?</p> <p>4 A. According to what's shown on</p> <p>5 the screen, it says here in Chinese, "This</p> <p>6 document is a new document." Based on that,</p> <p>7 I can determine that this document is a first</p> <p>8 version.</p> <p>9 MR. BALL: I didn't hear what</p> <p>10 you said. You "can determine" or you</p> <p>11 "can't determine"?</p> <p>12 I'm asking the translator what</p> <p>13 he said.</p> <p>14 THE INTERPRETER: The</p> <p>15 interpreter would repeat.</p> <p>16 A. I can, C-A-N, determine this is</p> <p>17 a first version.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. To your recollection, has --</p> <p>20 we'll rephrase.</p> <p>21 When the process change</p> <p>22 occurred to include zinc chloride in the</p> <p>23 process, was this guideline applied by ZHP?</p> <p>24 A. I'm sorry. Since I did not see</p>	<p style="text-align: right;">Page 56</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Is the answer --</p> <p>3 MR. BALL: Oppose the motion.</p> <p>4 MR. SLATER: I'm just saying it</p> <p>5 because you talked over me.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Is the answer yes or no?</p> <p>8 Please answer.</p> <p>9 MR. BALL: Objection to form.</p> <p>10 A. Could you repeat the question?</p> <p>11 BY MR. SLATER:</p> <p>12 Q. How did I know you were going</p> <p>13 to ask me that? I'll try it for the third</p> <p>14 time.</p> <p>15 Was this guideline applied and</p> <p>16 used when the process change to the zinc</p> <p>17 chloride process for valsartan was made?</p> <p>18 MR. BALL: Objection to form.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Yes or no.</p> <p>21 MR. BALL: Objection to form.</p> <p>22 A. During the process change for</p> <p>23 valsartan, we conducted corresponding work</p> <p>24 based on the requirements of ICH then, as</p>
<p style="text-align: right;">Page 55</p> <p>1 the effective date of this document, I cannot</p> <p>2 provide an accurate response to your</p> <p>3 question.</p> <p>4 Q. I can scroll -- rephrase.</p> <p>5 There is no effective date on</p> <p>6 the document. Not written on it.</p> <p>7 MR. BALL: Objection to form.</p> <p>8 I don't know if there's a question.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Here's the question. You --</p> <p>11 we'll rephrase.</p> <p>12 Was this guideline applied to</p> <p>13 the zinc chloride process change for</p> <p>14 valsartan? Yes or no.</p> <p>15 MR. BALL: Objection to form.</p> <p>16 A. During the process change for</p> <p>17 valsartan, we conducted our work based on the</p> <p>18 ICH and SOP requirements at that time.</p> <p>19 MR. SLATER: Move to strike.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Is the answer yes?</p> <p>22 MR. BALL: Oppose the motion.</p> <p>23 MR. SLATER: Move to strike.</p> <p>24 ///</p>	<p style="text-align: right;">Page 57</p> <p>1 well as the requirements of the SOP at that</p> <p>2 time.</p> <p>3 MR. SLATER: Move to strike.</p> <p>4 MR. BALL: Oppose the motion.</p> <p>5 MR. SLATER: Mr. Ball, he</p> <p>6 hasn't answered the question.</p> <p>7 MR. BALL: I believe he has, at</p> <p>8 least six or seven times.</p> <p>9 MR. SLATER: Tell me what I'm</p> <p>10 missing about the -- is the answer yes</p> <p>11 or no, then? Was this actually</p> <p>12 utilized with the process change?</p> <p>13 Because I can't figure it out from his</p> <p>14 answer.</p> <p>15 Would you tell me what that</p> <p>16 answer is?</p> <p>17 MR. BALL: Are you asking me or</p> <p>18 are you asking the witness?</p> <p>19 MR. SLATER: I'm asking you,</p> <p>20 because you keep saying his answer is</p> <p>21 responsive. So tell me whether or not</p> <p>22 the answer was yes or no.</p> <p>23 MR. BALL: I'm not going to --</p> <p>24 I'm not here to answer questions,</p>

<p style="text-align: right;">Page 58</p> <p>1 Adam. I'm sorry you don't like the                  2 answer you're getting from the                  3 witness.                  4 MR. SLATER: I don't not like                  5 the answer. He won't answer the                  6 question.                  7 MR. BALL: Adam, I'm sorry you                  8 don't like the answer. Again, you can                  9 take it up with the Court.                  10 MR. SLATER: Is that what you                  11 want me to do?                  12 MR. BALL: I want you to -- I                  13 don't want you to keep asking that                  14 same question over and over again                  15 because you don't like the answer                  16 you're given.                  17 MR. SLATER: It's not that I                  18 don't like it. It's that he won't                  19 answer the question, and I can't                  20 understand what he's saying. He's not                  21 addressing what I'm asking.                  22 I mean, I think there's some                  23 obligation by a lawyer to tell their                  24 client to be responsive in a federal</p>	<p style="text-align: right;">Page 60</p> <p>1 guideline is part of the SOP. I want to find                  2 out, which part are you referring to?                  3 MR. SLATER: Mr. Interpreter, I                  4 don't understand that. He's now                  5 saying that he doesn't understand your                  6 interpretation, and he's asking me to                  7 fix your interpretation?                  8 What's going on here? I mean,                  9 is that what he actually just said?                  10 A. Your question was translated by                  11 the interpreter, but it was very long.                  12 Through the interpreter, I heard that you                  13 referred to this guideline as part of the                  14 SOP, so I just wonder, which part of the SOP                  15 are you referring to?                  16 MR. SLATER: Move to strike all                  17 this nonresponsive evasion.                  18 MR. BALL: Oppose the motion.                  19 BY MR. SLATER:                  20 Q. Was this guideline utilized in                  21 connection with the zinc chloride process                  22 change? Yes or no.                  23 MR. BALL: Objection to form.                  24 A. During the zinc chloride</p>
<p style="text-align: right;">Page 59</p> <p>1 proceeding.                  2 MR. BALL: Adam, I believe he                  3 is being responsive. He's answering                  4 the question to the best of his                  5 ability.                  6 MR. SLATER: Really?                  7 MR. BALL: Yes.                  8 MR. SLATER: Okay. We'll try                  9 it one last time, and then we'll have                  10 our nice record.                  11 BY MR. SLATER:                  12 Q. Mr. Dong, was this guideline                  13 utilized as part of the evaluation of                  14 potential genotoxic impurities for the zinc                  15 chloride process change? Yes or no.                  16 And I'm asking you to either                  17 say yes or no.                  18 MR. BALL: Objection.                  19 You don't get to tell the                  20 witness how to answer a question,                  21 Adam.                  22 Objection to form.                  23 A. Your question is quite long. I                  24 just heard from the interpreter that this</p>	<p style="text-align: right;">Page 61</p> <p>1 process change, we conducted the                  2 corresponding work based on the requirements                  3 of ICH at that time, as well as the                  4 requirements of the SOP at that time.                  5 BY MR. SLATER:                  6 Q. Was this guideline one of those                  7 SOPs that was utilized?                  8 A. Judging from what is shown on                  9 the screen, I cannot tell the effective date                  10 of this SOP. I need to review the whole                  11 document in order to understand this SOP.                  12 MR. SLATER: Let's go off the                  13 record. I think it's time for a                  14 break, right?                  15 MR. BALL: It is time for a                  16 break.                  17 THE VIDEOGRAPHER: The time is                  18 9:35 a.m. Off the record.                  19 (Whereupon, a recess was                  20 taken.)                  21 THE VIDEOGRAPHER: The time is                  22 9:49 a.m. Back on the record.                  23 BY MR. SLATER:                  24 Q. The metadata for this document</p>

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1 says it was modified on June 17, 2011. I'm  
2 just telling you what the metadata says  
3 provided by your lawyer.  
4 Knowing that and looking at the  
5 document, you can look at it and tell me  
6 whether or not this guideline was applied to  
7 the zinc chloride process change for  
8 valsartan.  
9 MR. BALL: Objection to form.  
10 A. Judging from what has been  
11 shown on the screen, I cannot give you an  
12 accurate answer.  
13 As for the process change for  
14 valsartan, we conducted the corresponding  
15 work based on the requirements of ICH then  
16 and the requirements of SOP then.  
17 MR. SLATER: Move to strike  
18 from "as for" forward.  
19 MR. BALL: Oppose the motion.  
20 BY MR. SLATER:  
21 Q. What do you need to see in  
22 order to answer the question?  
23 A. What is your question?  
24 MR. SLATER: I'm going to take

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1 that as the witness has been asked  
2 enough times, he's going to refuse to  
3 answer and/or he's unprepared as a  
4 30(b)(6).  
5 We're going to move to the next  
6 document, and that's how we're going  
7 to conduct ourselves today.  
8 MR. BALL: Objection.  
9 MR. SLATER: Take the document  
10 down. We've made a full record on  
11 that issue with that document. I  
12 think that's sufficient to establish  
13 what's going on here.  
14 Now, what we're going to do  
15 next is pull up -- I'm going to be  
16 working with two documents. We have  
17 an English version and we have a  
18 Chinese version, both of which were  
19 provided by ZHP. I'm letting counsel  
20 know so they know what's going on.  
21 So I'm going to put on the  
22 screen -- what's the next exhibit?  
23 193 or 194?  
24 I'm asking the court reporter,

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1 actually.  
2 THE STENOGRAPHER: 194.  
3 (Whereupon, Exhibit Number  
4 ZHP-194 was marked for  
5 identification.)  
6 MR. SLATER: So let's put up  
7 Exhibit 194, which is ZHP00000161.  
8 And we're going to also mark as  
9 Exhibit 195 the English version of  
10 this document, which is ZHP01843066  
11 through 3119, which I suppose we can  
12 put into the chat so if defense  
13 counsel wants to look at the document  
14 I'm going to be using to refer to,  
15 he'll have the ability to do that.  
16 (Whereupon, Exhibit Number  
17 ZHP-195 was marked for  
18 identification.)  
19 MR. BALL: It's not up in the  
20 chat yet, Adam, but go ahead and get  
21 started.  
22 BY MR. SLATER:  
23 Q. Do you see Exhibit 195, titled  
24 "Change Request Form"?

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1 A. Indeed, on the screen there's a  
2 document shown to me. However, I cannot tell  
3 from the screen the exhibit number.  
4 Q. Do you see the "Title: Change  
5 Request Form" right there at the top of the  
6 document?  
7 A. In this document, on the upper  
8 part of this page, first row, middle column,  
9 in Chinese it says "Change Request Form."  
10 Q. Sir, I'd appreciate it if you  
11 can just answer "yes." It would be easier if  
12 you just say "yes" instead of repeating my  
13 question and saying -- and rereading the  
14 whole question back as your answer.  
15 A. I will tell you the truth.  
16 Q. Section 1, the Change Title is  
17 "Process Change for Valsartan Process II,"  
18 correct?  
19 MR. BALL: Mr. Hobbs, it's  
20 still not up in the chat.  
21 Go ahead.  
22 MR. SLATER: It's ZHP01843066.  
23 It's not a question for the  
24 witness. That's for my team, just to



<p style="text-align: right;">Page 66</p> <p>1 make sure they have the right one.                  2 Okay. What are we doing?                  3 MR. BALL: The only thing                  4 that's up in the chat is the ZH -- is                  5 the Bates number for it. There's no                  6 actual document.                  7 MS. CALDERON: Mr. Ball, this                  8 is Cheryll Calderon.                  9 The exhibit link was available                  10 in the chat. That's a public link for                  11 you and your witness.                  12 MR. BALL: I just tried to --                  13 MS. CALDERON: So it's that                  14 thing.                  15 MR. BALL: Oh. Hold on.                  16 Got it. Okay. Sorry.                  17 BY MR. SLATER:                  18 Q. Okay. Mr. Dong, are you                  19 familiar with this document, which is the                  20 "Process Change for Valsartan Process II"?                  21 Are you familiar with the                  22 document?                  23 A. On this page, the table where                  24 it says "Change Title," next to it, it says</p>	<p style="text-align: right;">Page 68</p> <p>1 MR. BALL: I'm not representing                  2 anything. Ask him whether or not it                  3 is.                  4 MR. SLATER: Counsel, we just                  5 don't agree. It's not a legitimate                  6 objection.                  7 MR. BALL: That's a --                  8 MR. SLATER: I'll ask a                  9 different question, because we all                  10 know it's the final version. So he                  11 can say this version all he wants, but                  12 we'll move on.                  13 BY MR. SLATER:                  14 Q. This is the change request form                  15 for the change to the zinc chloride --                  16 withdrawn.                  17 This is the change request form                  18 for the zinc chloride process for valsartan,                  19 correct?                  20 MR. SLATER: You know what?                  21 Stop. Stop. Time out. Withdrawn.                  22 Withdrawn.                  23 You know what? I got this                  24 figured out now. Thank you, Rick. I</p>
<p style="text-align: right;">Page 67</p> <p>1 "Process Change for Valsartan Process II."                  2 Q. The effective date is June 15,                  3 2011, correct? Do you see that at the top                  4 right?                  5 A. In the table, on the upper                  6 right corner, there is an effective date                  7 which says June 15, 2011. However, this                  8 effective date is not the effective date of                  9 the process change; rather, it is the                  10 effective date of this version of Change                  11 Request Form.                  12 Q. This is the final version of                  13 this document, correct?                  14 MR. BALL: Objection to form.                  15 MR. SLATER: One second.                  16 What's the objection?                  17 MR. BALL: Adam, you haven't                  18 laid a foundation. Ask -- you know,                  19 every time you say "correct," that's                  20 an improper way to form the question.                  21 You know it and I know it.                  22 MR. SLATER: Are you                  23 representing this isn't the final                  24 version of the document?</p>	<p style="text-align: right;">Page 69</p> <p>1 got it. We're good now.                  2 BY MR. SLATER:                  3 Q. Look in the left-hand column to                  4 the word "Proposed." Do you see that line                  5 that says "Proposed"?                  6 A. Can you scroll up the screen a                  7 little bit?                  8 Yes, I see it.                  9 Q. And it then says next to that,                  10 "Process II crude product preparation process                  11 would use zinc chloride as catalyst."                  12 Correct?                  13 A. In this table, in the line of                  14 proposed change, next to the word "Proposed,"                  15 there was a sentence written in Chinese which                  16 says "Process II crude product preparation                  17 process would use zinc chloride as catalyst."                  18 This is just one sentence of                  19 the content in that entry.                  20 MR. SLATER: Move to strike the                  21 "This is just one sentence" part.                  22 MR. BALL: Objection to form.                  23 Oppose the motion.                  24 ///</p>

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1 BY MR. SLATER:  
 2 Q. Mr. Dong, I asked you a bunch  
 3 of times, can you just answer with a "yes" if  
 4 the answer is a yes, instead of repeating the  
 5 whole question, please?  
 6 A. I will tell you the truth.  
 7 Q. Looking down --  
 8 MR. SLATER: Scroll down,  
 9 Cheryll, further down.  
 10 Okay. Perfect.  
 11 Q. Looking now at the box towards  
 12 the bottom, No. 4, it says, "If it is the  
 13 critical change?" And it says "Yes."  
 14 Do you see that?  
 15 A. At the bottom of this page, on  
 16 line 4, when it was asked if this is the  
 17 critical change, indeed, the box for "Yes"  
 18 was checked.  
 19 Q. At the very bottom of the  
 20 page --  
 21 MR. SLATER: Scroll down,  
 22 Cheryll, to the very bottom.  
 23 Okay. Stop.  
 24 Q. At the very bottom of the page,

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1 it says in the bottom left "Reference:  
 2 change control procedure (SMP-018)," correct?  
 3 A. On the bottom of the screen,  
 4 there is a line that says in Chinese,  
 5 "Reference document: change control procedure  
 6 (SMP-018)."  
 7 Q. That means that SMP applied to  
 8 this change request, correct?  
 9 A. The SMP in this document is the  
 10 reference for the platform of -- not  
 11 platform -- template, rather, of this  
 12 document.  
 13 Q. Go on to the next page, please,  
 14 page 2.  
 15 Box 2, "Change Control  
 16 Classification," the box checked is "Critical  
 17 Change," correct?  
 18 A. On the screen in the line of  
 19 "Change Control Classification," "Critical  
 20 Change" was indeed checked.  
 21 Q. The second box for "Minor  
 22 Change" was not checked, correct?  
 23 A. In the line of "Change Control  
 24 Classification," the option "Minor Change"

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1 was not checked.  
 2 MR. SLATER: Scroll down,  
 3 please, Cheryll.  
 4 A little more. More. A little  
 5 more.  
 6 Okay. Perfect.  
 7 Q. There's a box that says "Change  
 8 control Related Department(s)," and for the  
 9 "Process Change," a series of departments is  
 10 checked, correct?  
 11 Actually, you know what?  
 12 Withdraw that question. Forget it. I don't  
 13 care.  
 14 Looking now at the Explanation  
 15 Section, this provides the explanation for  
 16 why this was being done, correct?  
 17 MR. BALL: Objection to form.  
 18 A. On the screen in the  
 19 Explanation Section, there is a paragraph  
 20 written in Chinese.  
 21 MR. SLATER: Move to strike.  
 22 MR. BALL: Oppose the motion.  
 23 BY MR. SLATER:  
 24 Q. Sir, did I ask you what

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1 language it's written in?  
 2 A. I will tell the truth.  
 3 Q. You will tell the truth? I  
 4 need you to answer my questions. I didn't  
 5 ask you what language it's written in, so I  
 6 don't understand why you told me that.  
 7 Telling the truth is actually answering the  
 8 question responsively.  
 9 MR. BALL: Objection.  
 10 Harassment.  
 11 MR. SLATER: It's not  
 12 harassment, because, Counsel, you're  
 13 sitting there smiling, as if you think  
 14 this is a good idea that your client  
 15 has been doing this for over two hours  
 16 and has taken most of the time with  
 17 nonresponsive answers.  
 18 MR. BALL: Adam, I cannot help  
 19 the questions you ask.  
 20 MR. SLATER: No, he's not  
 21 answering.  
 22 Did I ask him what language it  
 23 was written in? No. So why don't you  
 24 tell him, please, "Sir, don't tell him



<p style="text-align: right;">Page 74</p> <p>1 what language it's in if he didn't ask                  2 that question."                  3 I mean, I don't understand why                  4 you wouldn't want to cooperate in good                  5 faith.                  6 MR. BALL: We are cooperating                  7 in good faith.                  8 MR. SLATER: No, you're not.                  9 MR. BALL: It's your questions.                  10 BY MR. SLATER:                  11 Q. Okay. So now we'll go to the                  12 next question.                  13 In the Explanation Section, it                  14 says, "This is a process change for current                  15 Valsartan manufacturing process II," then in                  16 parentheses, "(triethylamine hydrochloride                  17 process) in Workshop II. In crude product                  18 preparation process the catalyst for                  19 tetrazole forming reaction is changed from                  20 triethylamine hydrochloride to zinc chloride.                  21 In order to enhance conversion rate, reduce                  22 the level of D-valsartan via racemization and                  23 improve the yield or output quality of crude                  24 product. The bond acid reagent in acylation</p>	<p style="text-align: right;">Page 76</p> <p>1 section in the Explanation Section, the                  2 description in Chinese is basically                  3 consistent with the interpreter's translation                  4 of the opposing counsel's question.                  5 Q. What is "process validation" as                  6 that term is used there?                  7 A. Process validation is one of                  8 the managed activities under GMP.                  9 Q. What is process validation                  10 supposed to accomplish?                  11 A. The purpose of a process                  12 validation depends on the description                  13 specified in the process change plan. Or                  14 process validation plan, that is.                  15 Q. Go to the next page.                  16 Looking at Section 3 for the                  17 quality control department, in the                  18 Explanation Section it says, "The residue of                  19 zinc chloride and residue of solvents used in                  20 the process need to be tested for quality                  21 review. The relevant method validation                  22 should be completed."                  23 Do you see that?                  24 A. On the screen, under the</p>
<p style="text-align: right;">Page 75</p> <p>1 reaction process is changed to reduce cost.                  2 The process validation studies would be                  3 arranged in Workshop II of Chuannan East                  4 Zone."                  5 My only question is, did you                  6 see what I just read? It's a yes-or-no                  7 question.                  8 MR. BALL: Objection to form.                  9 A. What I read in the Explanation                  10 Section on the screen is basically consistent                  11 from the interpreter's interpretation of the                  12 opposing counsel's question.                  13 BY MR. SLATER:                  14 Q. Let's go to the next page,                  15 page 3.                  16 Under the "TE" section, in the                  17 Explanation Section it says, "This change                  18 request is agreed. The process validation                  19 should be performed. The manufacturing                  20 process instructions and batch record shall                  21 be revised. The stability studies shall be                  22 conducted. Yang Kai, November 27, 2011."                  23 Do you see what I just read?                  24 A. On the screen under the TE</p>	<p style="text-align: right;">Page 77</p> <p>1 section of quality control department in the                  2 Explanation Section, the description in                  3 Chinese is basically consistent with the                  4 interpretation of the plaintiffs' original                  5 statement.                  6 Q. The reason this -- rephrase.                  7 One of the reasons for this                  8 quality review is to identify any impurities                  9 due to the new process, correct?                  10 MR. BALL: Objection to form.                  11 A. I don't understand what the                  12 opposing counsel is referring to by "this                  13 review."                  14 BY MR. SLATER:                  15 Q. The quality review that is                  16 referenced in the Explanation Section that I                  17 just read.                  18 A. Can you repeat the complete                  19 question again?                  20 MR. SLATER: Read it back to                  21 him, please. The interpreter. You                  22 can read it back to him, right? I                  23 don't need to ask it again. You have                  24 it. Just please read it back to him</p>

<p style="text-align: right;">Page 78</p> <p>1 again.</p> <p>2 THE INTERPRETER: For the</p> <p>3 record, the interpreter is asked to</p> <p>4 repeat the rendition of a previous</p> <p>5 question.</p> <p>6 A. The QC department will, based</p> <p>7 on its departmental responsibility as well as</p> <p>8 the content of the change application, to</p> <p>9 conduct an assessment.</p> <p>10 MR. SLATER: Move to strike.</p> <p>11 MR. BALL: Oppose the motion.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Let's go now to the bottom of</p> <p>14 the document, the regulatory affairs section,</p> <p>15 please.</p> <p>16 Looking at the bottom of the</p> <p>17 document, the regulatory affairs section, in</p> <p>18 the explanation, the third sentence says,</p> <p>19 "This change is critical, and CEP major</p> <p>20 changes procedure would be applied."</p> <p>21 That's what it says, right?</p> <p>22 A. On the screen in the section of</p> <p>23 RA department in the Explanation Section, the</p> <p>24 third sentence here in this Chinese paragraph</p>	<p style="text-align: right;">Page 80</p> <p>1 A. This process change, as well as</p> <p>2 the work we conducted, were done based on the</p> <p>3 requirements of the SOP and the GMP.</p> <p>4 MR. SLATER: Move to strike.</p> <p>5 MR. BALL: Oppose the motion.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. I would appreciate it if you</p> <p>8 would make an effort to answer my question,</p> <p>9 Mr. Dong.</p> <p>10 A. I will tell the truth.</p> <p>11 Q. Okay. Then let's tell the</p> <p>12 truth in answering this question and actually</p> <p>13 answer the question I ask. That's what I'm</p> <p>14 asking.</p> <p>15 MR. BALL: Objection to form.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. I'll try it one last time with</p> <p>18 you on this one. New question.</p> <p>19 MR. SLATER: Interpreter, are</p> <p>20 you going to have to interpret what I</p> <p>21 just did? Because if you do, I'd</p> <p>22 rather you do it before I ask the</p> <p>23 question.</p> <p>24 Q. Line number 23 required that</p>
<p style="text-align: right;">Page 79</p> <p>1 says, "This change is critical, and CEP" -- I</p> <p>2 don't know how to pronounce the next English</p> <p>3 word, which is followed by "changes would be</p> <p>4 applied."</p> <p>5 MR. SLATER: Let's go to the</p> <p>6 next page. Perfect.</p> <p>7 Q. Looking now at Section 3, the</p> <p>8 quality assurance section, line 23 says,</p> <p>9 "Evaluate if it againsts cGMP code; (if so,</p> <p>10 describe the article and reject it)." And</p> <p>11 the box for "No" is checked?</p> <p>12 Do you see that?</p> <p>13 A. As shown on the screen, in the</p> <p>14 section for quality assurance department,</p> <p>15 line 23, it says here in Chinese, "Evaluate</p> <p>16 if it is against the cGMP code; (if so,</p> <p>17 describe the article that is against the code</p> <p>18 and reject that change request)." And the</p> <p>19 "No" box next to it was checked.</p> <p>20 Q. If this change was against cGMP</p> <p>21 code, it was supposed to be rejected. That</p> <p>22 is what that says, correct?</p> <p>23 MR. BALL: Objection.</p> <p>24 Foundation.</p>	<p style="text-align: right;">Page 81</p> <p>1 the change be rejected if this process change</p> <p>2 did not comply in any way with cGMP, correct?</p> <p>3 MR. BALL: Objection to form.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Yes or no.</p> <p>6 A. We conducted our work for any</p> <p>7 changes based on the requirements of our SOP</p> <p>8 as well as the GMP.</p> <p>9 MR. SLATER: Move to strike.</p> <p>10 That's not what I asked.</p> <p>11 MR. BALL: Oppose the motion.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Mr. Dong, you took an oath to</p> <p>14 answer these questions, so please answer the</p> <p>15 question.</p> <p>16 MR. BALL: Objection.</p> <p>17 A. I will tell the truth.</p> <p>18 For the process changes, we</p> <p>19 conducted our work under the condition of</p> <p>20 being in compliance with the SOP and the GMP.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. If your company did not comply</p> <p>23 with your SOPs -- rephrase.</p> <p>24 If your company did not comply</p>

<p style="text-align: right;">Page 82</p> <p>1 with GMP, the process change never should                  2 have been -- let me rephrase it. Let's get                  3 to the cut. Let's get to it. Hang on.                  4 Your company was legally                  5 required to comply with GMP with the process                  6 change, correct?                  7 MR. BALL: Objection to form.                  8 A. What legal requirements are you                  9 referring to?                  10 BY MR. SLATER:                  11 Q. The regulations of the United                  12 States of America, including the FDA.                  13 MR. BALL: Objection to form.                  14 A. We conducted our work for our                  15 process change under the premise that they                  16 are in compliance with the requirement of                  17 GMP, including the US GMP.                  18 MR. SLATER: Move to strike.                  19 MR. BALL: Oppose the motion.                  20 BY MR. SLATER:                  21 Q. What I asked is if your company                  22 was required to comply with GMP in order to                  23 be in compliance with United States law.                  24 MR. BALL: Objection to form.</p>	<p style="text-align: right;">Page 84</p> <p>1 Explanation Section on the first line, there                  2 was a sentence in Chinese which fits this                  3 description.                  4 Q. With regard to this change for                  5 this API, what was the purpose of the process                  6 validation?                  7 A. As for the purpose of the                  8 process validation for valsartan this time, I                  9 need to check the process validation plan.                  10 Q. What was the purpose of the                  11 process validation?                  12 A. Which process validation are                  13 you referring to?                  14 Q. The process validation referred                  15 to in this document for this process change                  16 that you were designated by your company to                  17 testify about.                  18 A. As for the purpose of the                  19 process validation for this proposed process                  20 change for the valsartan, I need to check the                  21 process validation plan in order to provide                  22 you with an accurate answer.                  23 In general, process validation                  24 is to confirm whether the product can be</p>
<p style="text-align: right;">Page 83</p> <p>1 BY MR. SLATER:                  2 Q. I didn't ask if you did comply;                  3 I asked if you were required to comply. Yes                  4 or no.                  5 MR. BALL: Objection to form.                  6 A. We would conduct our work in                  7 compliance with the corresponding                  8 requirements of GMP and SOP.                  9 MR. SLATER: Move to strike.                  10 MR. BALL: Oppose the motion.                  11 MR. SLATER: All right. We'll                  12 just keep making our record. I mean,                  13 I just can't get an answer to a                  14 question from this witness.                  15 Scroll down a little more,                  16 Cheryll, please.                  17 Thanks. Perfect.                  18 Q. Here on page 5 of this document                  19 in the Explanation Section, number 1, it says                  20 "Technology department prepare process                  21 validation protocol, and organize process                  22 validation."                  23 Do you see that?                  24 A. On the screen, in the</p>	<p style="text-align: right;">Page 85</p> <p>1 stably manufactured under the current scale                  2 of the process.                  3 Q. Mr. Dong, did you say you have                  4 two computer screens in front of you?                  5 A. That is correct.                  6 Q. So you can actually -- when I                  7 ask a yes-or-no question, you can actually                  8 answer the question with a yes or no when you                  9 choose to, apparently, is that correct?                  10 MR. BALL: Objection to form.                  11 A. Can you repeat your question                  12 here?                  13 BY MR. SLATER:                  14 Q. No, I can't.                  15 Your company was supposed to                  16 perform a risk assessment as part of the                  17 process validation -- rephrase.                  18 Your company was supposed to                  19 perform a risk assessment as part of the                  20 process change evaluation, correct?                  21 MR. BALL: Objection to form.                  22 A. What do you mean by "was                  23 supposed to"?                  24 ///</p>

<p style="text-align: right;">Page 86</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Required to.</p> <p>3 A. We conducted corresponding work</p> <p>4 based on the requirements of ICH and SOP.</p> <p>5 MR. SLATER: Move to strike.</p> <p>6 MR. BALL: Oppose the motion.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. I didn't ask you what you did;</p> <p>9 I asked you what you were required to do. So</p> <p>10 please answer that question.</p> <p>11 A. We conducted corresponding work</p> <p>12 based on the requirements of ICH and SOP. I</p> <p>13 mean the ICH and SOP at that time.</p> <p>14 MR. SLATER: Move to strike.</p> <p>15 MR. BALL: Oppose the motion.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Was your company required to</p> <p>18 perform a risk assessment in connection with</p> <p>19 the process change to the zinc chloride</p> <p>20 process? Yes or no.</p> <p>21 A. In 2011 for the process change</p> <p>22 using zinc chloride for valsartan, we</p> <p>23 conducted corresponding work based on the</p> <p>24 requirements of ICH and SOP at that time.</p>	<p style="text-align: right;">Page 88</p> <p>1 What is the purpose of</p> <p>2 Attachment 2 as part of this document? Why</p> <p>3 is it there?</p> <p>4 A. On the screen it is shown the</p> <p>5 Attachment 2 to the change request form for</p> <p>6 the zinc chloride process change in 2011.</p> <p>7 Attachment 2 is the change action list.</p> <p>8 Q. What is the change action list?</p> <p>9 What is the significance of that?</p> <p>10 A. The change action list details</p> <p>11 the actions each department needed to take.</p> <p>12 Q. Those actions had to be taken</p> <p>13 in order for the change to be approved,</p> <p>14 correct?</p> <p>15 A. The change action list is</p> <p>16 required by the SOP as one of the</p> <p>17 requirements.</p> <p>18 Q. Item number 5 --</p> <p>19 MR. SLATER: Let's go down to</p> <p>20 number 5, please, Cheryll.</p> <p>21 Q. Item number 5 indicates that</p> <p>22 regulatory affairs updates the DMF and</p> <p>23 notifies customers and authorities, correct?</p> <p>24 A. The Chinese writing in item</p>
<p style="text-align: right;">Page 87</p> <p>1 MR. SLATER: Move to strike.</p> <p>2 MR. BALL: Oppose the motion.</p> <p>3 MR. SLATER: For the</p> <p>4 interpreter, I think we might be at</p> <p>5 your time. I can continue, but I just</p> <p>6 want to make sure. Someone just</p> <p>7 pinged me that you might be up to your</p> <p>8 time.</p> <p>9 MR. BALL: Yeah, we're at</p> <p>10 63 minutes, Adam.</p> <p>11 MR. SLATER: All right. Let's</p> <p>12 go off the record.</p> <p>13 THE VIDEOGRAPHER: The time is</p> <p>14 10:56 a.m. Off the record.</p> <p>15 (Whereupon, a recess was</p> <p>16 taken.)</p> <p>17 THE VIDEOGRAPHER: The time is</p> <p>18 11:15 a.m. Back on the record.</p> <p>19 MR. SLATER: Let's go now,</p> <p>20 Cheryll, please, to Attachment 2.</p> <p>21 Perfect.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. This is Attachment 2 to the</p> <p>24 change request form.</p>	<p style="text-align: right;">Page 89</p> <p>1 number 5 on the screen does say so.</p> <p>2 Q. Go to the next page, please.</p> <p>3 The Bates number is 073, are the last three</p> <p>4 digits.</p> <p>5 MR. SLATER: And please go to</p> <p>6 item 5 as well, Cheryll.</p> <p>7 Q. This page indicates that all</p> <p>8 actions had been implemented, the change</p> <p>9 control could be approved and closed,</p> <p>10 correct?</p> <p>11 A. I'm sorry. I'm not sure which</p> <p>12 section the plaintiffs' attorney is referring</p> <p>13 to specifically.</p> <p>14 Q. In the top section, number 1,</p> <p>15 "If all actions have been implemented?" It</p> <p>16 says "Yes."</p> <p>17 Number 2 says, "If approve to</p> <p>18 close up the change control?" And it says</p> <p>19 "Yes." Correct?</p> <p>20 A. That is correct.</p> <p>21 Q. Number 3 says that the first</p> <p>22 product batch number produced after the</p> <p>23 change would be number C5355-12-001, correct?</p> <p>24 A. That is correct.</p>

<p style="text-align: right;">Page 90</p> <p>1 Q. Going now in the Explanation              2 Section, number 5 says, "December 20, 2013,              3 regulatory affairs completed the DMF update,              4 submission to authority and notification to              5 customers." Correct?              6 A. On the screen in the              7 Explanation Section, there is a paragraph,              8 item number 5, it says, "On December 20,              9 2013, the regulatory affairs department              10 completed the update of the DMF document and              11 submitted it to the authority, in addition to              12 notification to the customers."              13 Q. Why was it required as part of              14 this process change to update the DMF?              15 A. Our process change requires the              16 approval from FDA, per FDA's regulations, in              17 order to implement the change in the US              18 market. That's the reason why the DMF              19 document needed to be updated.              20 Q. Are you aware that the FDA              21 doesn't approve a DMF?              22 MR. BALL: Objection to form.              23 Outside the scope of the 30(b)(6).              24 I assume you're asking him in</p>	<p style="text-align: right;">Page 92</p> <p>1 dialogue between the counsel?              2 MR. SLATER: No. No.              3 A. I don't remember the pending              4 question.              5 BY MR. SLATER:              6 Q. Are you aware that the FDA does              7 not approve a DMF? It's not for that              8 purpose?              9 MR. BALL: Same objection.              10 BY MR. SLATER:              11 Q. Are you aware of that?              12 A. The question from the              13 plaintiffs' attorney was indeed beyond the              14 scope of my testimony as the corporate              15 witness.              16 However, based on the personal              17 understanding, for our process change, we              18 were obligated to submit the updated DMF              19 document to FDA for the authority.              20 Q. You were required by your              21 internal standard operating procedures, but              22 the FDA did not actually approve the DMF,              23 correct?              24 MR. BALL: Objection to form,</p>
<p style="text-align: right;">Page 91</p> <p>1 his individual capacity, Adam?              2 MR. SLATER: I'm asking -- it's              3 part of their change control request              4 document. It's part of his topic.              5 This document is at the heart of his              6 topic. I just --              7 MR. BALL: Adam, I'm asking --              8 Adam, I'm asking you if you're asking              9 him in his individual capacity whether              10 or not he knows it's something that              11 FDA requires or doesn't require.              12 MR. SLATER: I'm asking him in              13 his capacity as a 30(b)(6) witness who              14 just made an affirmative statement in              15 his capacity as a 30(b)(6) witness.              16 He said something, and I'm              17 asking him a question about what he              18 said as an answer to a question within              19 the scope of his topic.              20 MR. BALL: I believe it's              21 outside the scope.              22 He can answer.              23 THE INTERPRETER: Counsel, does              24 the interpreter need to translate the</p>	<p style="text-align: right;">Page 93</p> <p>1 and outside the scope.              2 A. Counsel's question was indeed              3 beyond the scope of my testimony as a              4 corporate witness.              5 MR. BALL: He should answer              6 anyway, if he can.              7 A. However, to the best of my              8 personal knowledge, it was our regulatory              9 affairs department's responsibility to              10 conduct the communication between ZHP and the              11 authorities. That's their job description.              12 BY MR. SLATER:              13 Q. We'll come back to the DMF in a              14 second.              15 Are you -- you said before              16 you're looking at two screens, right?              17 A. That is correct.              18 Q. All right. What's on the two              19 screens?              20 A. The computer I'm using right              21 now is the one that I use to conduct this              22 Zoom meeting. On the screen it shows the              23 exhibit.              24 The other computer shows the</p>



<p style="text-align: right;">Page 94</p> <p>1 screen saver right now. There's nothing                  2 ongoing in the other computer.                  3 Q. When I asked you the questions                  4 about the DMF, why did you say that the                  5 question was beyond the scope of the topics                  6 of your testimony as a corporate witness?                  7 Why did you say that?                  8 A. As a corporate witness, I am                  9 supposed to, or I am responsible for the                  10 discussion regarding those topics.                  11 Q. Do you remember the beginning                  12 of the deposition when you couldn't remember                  13 the topics?                  14 MR. BALL: Objection to form.                  15 BY MR. SLATER:                  16 Q. Now you're an expert on the                  17 topics --                  18 MR. BALL: Objection to form.                  19 BY MR. SLATER:                  20 Q. -- and you repeat objections?                  21 Why is that, sir?                  22 MR. BALL: Objection to form.                  23 A. As for the questions I'm                  24 supposed to answer as a corporate witness, I</p>	<p style="text-align: right;">Page 96</p> <p>1 BY MR. SLATER:                  2 Q. When you said the question was                  3 beyond the scope of your testimony, did you                  4 come up with that on your own, or were you                  5 repeating the objection by your attorney?                  6 MR. BALL: Objection to form.                  7 A. I came up with the                  8 corresponding judgment. That was because my                  9 obligation was to answer the questions                  10 related to the technical department.                  11 As for the DMF document, that                  12 was related to the regulatory affairs                  13 activities. I believe the colleagues of mine                  14 from the regulatory affairs department should                  15 answer those questions.                  16 BY MR. SLATER:                  17 Q. The change request form --                  18 rephrase.                  19 You agree with me that any                  20 information put in that DMF based on this                  21 change process needed to be completely                  22 accurate, correct?                  23 MR. BALL: Objection to form.                  24 And outside of the scope of the</p>
<p style="text-align: right;">Page 95</p> <p>1 do have some understanding, or I may say I do                  2 recall some of the topics.                  3 However, if you ask me to                  4 accurately recite all the topics I need to                  5 respond to as a corporate witness or you want                  6 me to give an accurate response to your                  7 questions as to what topics I'm supposed to                  8 answer as a corporate witness, I would like                  9 you to present that document to me for my                  10 response.                  11 MR. BALL: And, for the record,                  12 that was the first document that                  13 Mr. Slater put up, and he did not show                  14 any of the corporate topics.                  15 MR. SLATER: I'm not really                  16 sure why I would. Your client doesn't                  17 read English.                  18 MR. BALL: You could have had                  19 them translated, Adam, by the                  20 translator. That's why we have him.                  21 MR. SLATER: I didn't think it                  22 was necessary for what I wanted to ask                  23 him. But thank you for your kind                  24 advice.</p>	<p style="text-align: right;">Page 97</p> <p>1 30(b)(6) topics.                  2 A. I do not understand what the                  3 opposing counsel was referring to with regard                  4 to any DMF information.                  5 BY MR. SLATER:                  6 Q. Okay. Go to the next page,                  7 please. This is -- let me just get to it.                  8 On the English, it's 074 is the                  9 last three digits -- I'm not done. And in                  10 the Chinese, it's 0169 are the last digits of                  11 the Bates number.                  12 Section -- rephrase.                  13 The title of this page says                  14 "Valsartan Process II (Zinc Chloride Process)                  15 Changes Summary," and Section I is "Reasons                  16 for Changes."                  17 And it says in the first                  18 paragraph, "There were some defects and                  19 inadequacies for the previous manufacturing                  20 process of Valsartan, such as the low yield                  21 in some steps, high production cost, three                  22 wastes pollution problems, etcetera."                  23 Do you see where I just read?                  24 A. On the screen, I did find what</p>



<p style="text-align: right;">Page 98</p> <p>1 the interpreter provided as the rendition.                  2 Q. In Section I on page Bates 0169                  3 under "Reasons for Changes," in the third                  4 line it says, "From 2010, ZHP had                  5 commissioned Shanghai SynCore Technologies,                  6 Inc. to optimize the previous synthesis                  7 process of Valsartan (Process II,                  8 Trimethylamine Hydrochloride Process),                  9 focusing on the new tetrazole formation                  10 process development of crude step."                  11 Do you see that? I want to ask                  12 you a question about it. Literally the                  13 question is, do you see that.                  14 A. On the screen, I do see the                  15 interpreter's rendition of the opposing                  16 counsel's statement. However, it is just one                  17 sentence in the paragraph under Section I.                  18 MR. SLATER: Move to strike                  19 that last part saying it was just one                  20 sentence.                  21 MR. BALL: Oppose the motion.                  22 BY MR. SLATER:                  23 Q. Further down in that paragraph,                  24 there's a reference to "the lab-scale studies</p>	<p style="text-align: right;">Page 100</p> <p>1 interpreter, it says "Shanghai                  2 SynCore," so I don't know why you keep                  3 saying "Kesheng." I'm not sure where                  4 Kesheng is coming from. It says                  5 SynCore in this. I don't know what                  6 Kesheng is.                  7 THE INTERPRETER: For the                  8 record, the English document had a                  9 misinterpretation. The interpreter                  10 provided the rendition based on the                  11 witness' testimony, which was                  12 consistent with what's written here in                  13 Chinese.                  14 MR. SLATER: I mean, my                  15 checkers don't agree, but -- I don't                  16 know what to do.                  17 MR. BALL: Hey, Adam? To the                  18 best of my knowledge, it's referring                  19 to SynCore also. Just putting that                  20 out there.                  21 MR. SLATER: Yeah. I would                  22 think it's got to be accurate.                  23 MR. BALL: Right.                  24 MR. SLATER: If SynCore -- it</p>
<p style="text-align: right;">Page 99</p> <p>1 results (R&amp;D report No.: SC-1141)."                  2 What does that mean, "lab-scale                  3 studies results"?                  4 A. On the screen under Section I,                  5 reasons for the change, the paragraph under                  6 it, in the last sentence there was this                  7 reference based on the lab study -- lab-scale                  8 study results SC-1141. That refers to the                  9 research and development report provided by                  10 Shanghai Kesheng Company Limited, Kesheng                  11 spelled as K-E-S-H-E-N-G Company Limited.                  12 MR. SLATER: Move to strike.                  13 MR. BALL: Oppose the motion.                  14 BY MR. SLATER:                  15 Q. What was the purpose of the                  16 lab-scale studies results referred to under                  17 Section I where it says "Reasons for                  18 Changes"?                  19 A. The lab-scale study result                  20 mentioned in the Reasons for Changes under                  21 Section I of this document on the screen                  22 refers to the lab-scale study report provided                  23 by Kesheng, spelled as K-E-S-H-E-N-G.                  24 MR. SLATER: For the</p>	<p style="text-align: right;">Page 101</p> <p>1 was carefully, I assume, translated                  2 into the English here.                  3 MR. BALL: Yeah. So, to the                  4 best of my knowledge, it's SynCore                  5 also. So...                  6 MR. SLATER: Okay. I guess                  7 I'll move to strike because I still                  8 don't --                  9 THE INTERPRETER: The                  10 interpreter --                  11 MR. SLATER: -- know what the                  12 purpose of the lab-scale studies was,                  13 but it's okay.                  14 THE INTERPRETER: The                  15 interpreter interprets what he hears.                  16 MR. SLATER: Yeah. No, I                  17 understand. I'm just -- we're trying                  18 to figure out why he's saying                  19 "Kesheng" when the official document                  20 from ZHP says "Shanghai SynCore" as                  21 the interpretation. So I'm trying to                  22 figure out why he'd be saying                  23 "Kesheng" if the English document says                  24 "Shanghai SynCore Technologies."</p>

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1 BY MR. SLATER:  
 2 Q. Let's go to Section II.  
 3 MR. BALL: I'm sorry. What are  
 4 we doing?  
 5 MR. SLATER: Looking at Section  
 6 II. Yeah, let me -- I'll start over.  
 7 We're looking at Section II.  
 8 I don't know where we're going  
 9 there. You don't have to scroll down.  
 10 MR. BALL: Yeah, I'm sorry. I  
 11 thought you said "go back to." That's  
 12 why I was confused.  
 13 MR. SLATER: No, no. I'm  
 14 talking to Cheryll. I actually didn't  
 15 want to -- yeah, keep going a little  
 16 bit more.  
 17 Perfect. And you'll just walk  
 18 down with me, Cheryll.  
 19 BY MR. SLATER:  
 20 Q. Under Section II, there's a box  
 21 titled "Raw Materials Changes Comparison."  
 22 Let's go to the next page now,  
 23 where there's the comparison of the raw  
 24 materials.

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1 I'm withdrawing the question.  
 2 I'm going to go to the next section. I'm  
 3 sorry. I'm going to go to the next section.  
 4 Looking now at the box titled 2  
 5 on -- 170 is the Bates number. The box  
 6 starts on that page, and the title is "Main  
 7 Materials Charging and Production Capacity  
 8 Comparison." And if we scroll to the next  
 9 page --  
 10 MR. SLATER: I want to go to  
 11 the middle of the page, please.  
 12 Q. If you go down to the "Crude"  
 13 section, this indicates that triethylamine  
 14 hydrochloride was replaced with zinc  
 15 chloride.  
 16 Do you see that?  
 17 A. On the screen in a box for  
 18 crude product step, the description in  
 19 Chinese does say that triethylamine  
 20 hydrochloride was replaced with zinc  
 21 chloride.  
 22 However, the title of this  
 23 table that the opposing counsel just referred  
 24 to cannot be seen on the screen.

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1 MR. SLATER: Move to strike  
 2 from "however" forward.  
 3 MR. BALL: Oppose the motion.  
 4 BY MR. SLATER:  
 5 Q. The next line is "Sodium  
 6 azide," and it says 112.5 kilograms is  
 7 replaced by sodium azide 250 kilograms.  
 8 Do you see that?  
 9 A. On the screen, in the box for  
 10 crude products step, there is a line where  
 11 the Chinese indicates that sodium azide was  
 12 increased from 112.5 kilograms to  
 13 250 kilograms.  
 14 Q. If you go down three more  
 15 boxes, it indicates that sodium nitrite was  
 16 increased from 100 kilograms to  
 17 250 kilograms, correct?  
 18 A. On the screen, in the box for  
 19 crude product step, there was a line where  
 20 the Chinese description indicates the amount  
 21 of sodium nitrite used was increased from  
 22 100 kilograms to 250 kilograms.  
 23 Q. And if we go up to the prior  
 24 box for a moment -- you can leave it where it

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1 is because we can see the last entry -- this  
 2 indicates in the "Acylation" section that  
 3 DMF, dimethylformamide, had been added to the  
 4 process, correct?  
 5 A. On the screen, in the box for  
 6 the staff of acetylation --  
 7 THE INTERPRETER: The  
 8 interpreter's correction.  
 9 A. On the screen, in the box of  
 10 "Acylation," there is a line where it  
 11 indicated that DMF was added to the process.  
 12 Q. As part of the change control  
 13 process, these changes in the substances used  
 14 to manufacture valsartan had to be evaluated  
 15 for impurities, correct?  
 16 MR. BALL: Objection to form.  
 17 A. We conducted corresponding work  
 18 based on the requirements of ICH and SOP.  
 19 What I mean is the ICH and SOP at that time.  
 20 BY MR. SLATER:  
 21 Q. So your answer is yes, you were  
 22 required to perform a risk assessment for  
 23 potential impurities resulting from these  
 24 changes in the substances used to manufacture

<p style="text-align: right;">Page 106</p> <p>1 valsartan, correct?</p> <p>2 MR. BALL: Objection to form.</p> <p>3 THE VIDEOGRAPHER: It's just</p> <p>4 his connection.</p> <p>5 MR. BALL: I was going to say,</p> <p>6 did we just lose his connection?</p> <p>7 THE VIDEOGRAPHER: That's his</p> <p>8 internet lagging behind. We're going</p> <p>9 to know in about five to ten seconds</p> <p>10 if he disconnected or not, or whether</p> <p>11 he regroups.</p> <p>12 I think he's going to</p> <p>13 disconnect. Do you guys want to go</p> <p>14 off the record?</p> <p>15 MR. BALL: Why don't we go off</p> <p>16 the record.</p> <p>17 THE VIDEOGRAPHER: The time is</p> <p>18 12:04 p.m. Off the record.</p> <p>19 (Off the record.)</p> <p>20 THE VIDEOGRAPHER: The time is</p> <p>21 12:05 p.m. We are back on the record.</p> <p>22 A. I'm sorry, I just lost the</p> <p>23 connection. Would the interpreter like me to</p> <p>24 repeat my response?</p>	<p style="text-align: right;">Page 108</p> <p>1 sentences in this box.</p> <p>2 MR. SLATER: Move to strike the</p> <p>3 observation that "This is just one</p> <p>4 sentence."</p> <p>5 Q. I thank you for telling me</p> <p>6 that.</p> <p>7 MR. BALL: Oppose the motion.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Number 2 says, "Sodium azide</p> <p>10 used for the quenching is increased due to</p> <p>11 the increase of sodium azide."</p> <p>12 That should actually say sodium</p> <p>13 nitrite used for the quenching is increased,</p> <p>14 correct?</p> <p>15 A. On the screen, in a box for</p> <p>16 crude product step, there is a sentence in</p> <p>17 Chinese which says, "The amount of sodium</p> <p>18 nitrite used in the quenching step was</p> <p>19 increased because that was a corresponding</p> <p>20 increase based on the increase of the charged</p> <p>21 amount of sodium azide."</p> <p>22 Over here the wording "sodium</p> <p>23 nitrite used in the quenching" means the</p> <p>24 amount of sodium nitride used in the</p>
<p style="text-align: right;">Page 107</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Yes.</p> <p>3 A. Just now the plaintiffs'</p> <p>4 attorney failed to accurately describe what I</p> <p>5 wanted to express.</p> <p>6 What I wanted to express is</p> <p>7 that in 2011 for the process change using</p> <p>8 zinc chloride in the manufacturing of</p> <p>9 valsartan, based on the ICH and SOP at that</p> <p>10 time, we conducted corresponding work.</p> <p>11 MR. SLATER: Move to strike.</p> <p>12 MR. BALL: Oppose the motion.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Underneath the box where I was</p> <p>15 just reading from, in number 1 it says that</p> <p>16 "The tetrazole formation system is changed</p> <p>17 and the quantity of sodium azide is</p> <p>18 increased," correct?</p> <p>19 A. On the screen, in the box for</p> <p>20 crude product step, there is a sentence in</p> <p>21 Chinese which says, "For crude product, the</p> <p>22 tetrazole reaction system has changed. The</p> <p>23 amount of sodium azide used is increased."</p> <p>24 This sentence is just one sentence among many</p>	<p style="text-align: right;">Page 109</p> <p>1 quenching step.</p> <p>2 Q. Thank you for that.</p> <p>3 So in the Chinese, it's</p> <p>4 accurate. The English translation said</p> <p>5 "sodium azide used for the quenching." It</p> <p>6 should have said "sodium nitrite"?</p> <p>7 A. I am sorry. I cannot read the</p> <p>8 English version. The interpreter did not</p> <p>9 translate the English version to me, so I</p> <p>10 have no idea what the English version says.</p> <p>11 MR. SLATER: Go to, if we</p> <p>12 could -- you know, I just looked at</p> <p>13 what time it is. We can go off the</p> <p>14 record and break for the night.</p> <p>15 MR. BALL: Okay. Can I get</p> <p>16 when we go off how much time we've</p> <p>17 gone total?</p> <p>18 THE VIDEOGRAPHER: We went for</p> <p>19 four hours and 12 minutes.</p> <p>20 But the time is 12:14 p.m. We</p> <p>21 are going off the record.</p> <p>22 (Whereupon, the deposition was</p> <p>23 adjourned.)</p> <p>24</p>

# CERTIFICATE

I, MAUREEN O'CONNOR POLLARD, Registered Diplomat Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, PENG DONG, was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

MAUREEN O'CONNOR POLLARD  
NCRA Registered Diplomate Reporter  
Realtime Systems Administrator  
Certified Shorthand Reporter  
Notary Public

Dated: March 30, 2021

ERRATA

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## INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

### ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do  
Hereby certify that I have read the foregoing  
pages, and that the same is a correct  
transcription of the answers given by me to  
the questions therein propounded, except for  
the corrections or changes in form or  
substance, if any, noted in the attached  
Errata Sheet.

---

PENG DONG
DATE

Subscribed and sworn  
To before me this  
\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_\_.

My commission expires: \_\_\_\_\_

Notary Public

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